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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/810,741	03/26/2004	Donald B. Borders	660081.425C1	9685
7278	7590	08/30/2005	EXAMINER	
DARBY & DARBY P.C. P. O. BOX 5257 NEW YORK, NY 10150-5257			RUSSEL, JEFFREY E	
			ART UNIT	PAPER NUMBER
			1654	

DATE MAILED: 08/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/810,741	BORDERS ET AL.
	Examiner	Art Unit
	Jeffrey E. Russel	1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 26 March 2004.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-24 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>20041220;20050525</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1654

1. The claim for priority under 35 U.S.C. 119(e) and 120 is objected to because the claim for priority set forth at page 1, lines 3-11, of the specification does not agree with the claim for priority set forth in the Application Data Sheet. In the claim for priority set forth in the specification, this application directly claims priority based upon application serial no. 09/760,328 (note the use of “and is” at line 6). In the claim for priority set forth in the Application Data Sheet, this application directly claims priority based upon application serial no. 09/948,374, which directly claims priority based upon application serial no. 09/760,328. Further, with respect to the claim for priority set forth in the specification, it would not be proper for this application to claim priority directly upon application serial no. 09/760,328 because there is no copendency between the two applications. Finally, to the extent that Applicants recite a claim for priority as the first sentence of the specification, the status of the parent applications should be updated. Correction is required.
2. To the extent that Applicants intend to claim priority under 35 U.S.C. 120 directly upon application serial no. 09/760,328 (see section 1 above), the copy of the declaration under 37 CFR 1.63 filed March 26, 2004 is objected to because the submission of a copy of an oath or declaration is not permitted in a continuation-in-part application. See 37 CFR 1.63(d). Correction is required.
3. The abstract of the disclosure is objected to because it is insufficiently detailed. Further details concerning the types of acidic lipopeptide antibiotics and the isolation steps are required. Correction is required. See MPEP § 608.01(b).
4. Claims 15-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as

the invention. Claim 15 is unclear as to which solution's pH is being adjusted to a basic pH, and at what point during the method the solution's pH is being adjusted. The original fermentation broth or culture's pH is adjusted to acidic pH in claim 10, and the second aqueous solution's pH is adjusted to about pH 7.0 in claim 13, and it is unclear whether or not Applicants intended to adjust the pH of one of these solutions which has just had or will have its pH adjusted to a different value. It is possible that the pH adjustment specified in claim 13 is for the second aqueous solution prior to the centrifugate suspension step, and that the pH adjustment specified in claim 15 is for the solution resulting after the centrifugate suspension step and prior to extraction step of the independent claim. In any event, clarification is required.

5. Claims 18-22 are objected to because of the following informalities: At claim 18, line 6, "fourth" should be inserted before "aqueous". Appropriate correction is required.

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 1-24 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-27 of U.S. Patent No. 6,716,962. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '962 patent clearly anticipate the instant claims.

Art Unit: 1654

8. Claims 1-5, 8-18, and 22-24 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent No. 6,511,962. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '962 patent clearly anticipate instant claims 1-5, 8, 11, 12, 15-18, and 22-24. With respect to instant claims 9, 10, 13, and 14, while the '962 patent does not claim the divalent cation ratio, temperature, and pH recited in these claims, it would have been obvious to one of ordinary skill in the art to determine all operable and optimal divalent cation ratios, temperatures, and pHs for the corresponding method steps claims in the '962 patent because reactant ratio, temperature, and pH are art-recognized result-effective variables which are routinely determined and optimized in the chemical and extraction arts.

9. Claims 1-5, 8-18, and 22-24 are directed to an invention not patentably distinct from claims 1-15 of commonly assigned U.S. Patent No. 6,511,962. Specifically, see the above obviousness-type double patenting rejection.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302). Commonly assigned U.S. Patent No. 6,511,962, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee is required under 37 CFR 1.78(c) and 35 U.S.C. 132 to either show that the conflicting inventions were commonly owned at the time the invention in this application was

Art Unit: 1654

made or to name the prior inventor of the conflicting subject matter. Failure to comply with this requirement will result in a holding of abandonment of the application.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications filed on or after November 29, 1999.

10. Instant claims 1-24 are deemed to be entitled under 35 U.S.C. 119(e) to the benefit of the filing date of provisional application 60/286,254 because the '254 application, under the test of 35 U.S.C. 112, first paragraph, discloses the instant claimed invention.

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for the purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

Art Unit: 1654

claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

For the purposes of this invention, the level of ordinary skill in the art is deemed to be at least that level of skill demonstrated by the patents in the relevant art. Joy Technologies Inc. v. Quigg, 14 USPQ2d 1432 (DC DC 1990). One of ordinary skill in the art is held accountable not only for specific teachings of references, but also for inferences which those skilled in the art may reasonably be expected to draw. In re Hoeschele, 160 USPQ 809, 811 (CCPA 1969). In addition, one of ordinary skill in the art is motivated by economics to depart from the prior art to reduce costs consistent with desired product properties. In re Clinton, 188 USPQ 365, 367 (CCPA 1976); In re Thompson, 192 USPQ 275, 277 (CCPA 1976).

12. Claim 23 is rejected under 35 U.S.C. 102(b) as being anticipated by Umezawa et al (U.S. Patent No. 3,639,582). Umezawa et al teach contacting an aqueous solution of laspartomocycin, which has a pI of 2.6, with butanol in order to extract the laspartomycin. The laspartomycin is recovered from the butanol by concentration in vacuo. See, e.g., column 1, line 53; column 5, lines 11-33; and column 8, lines 18-35.

13. Claim 23 is rejected under 35 U.S.C. 102(b) as being anticipated by Hamill et al (U.S. Patent No. 4,331,594). Hamill et al teach contacting an aqueous solution of the antibiotic A-21978C with n-butanol in order to extract the A-21978C. The A-21978C is then recovered from the n-butanol by concentration under vacuum. See, e.g., column 4, lines 41-54; column 15, lines 23-25; column 22, lines 10-13; and column 25, line 62 - column 26, line 6.

14. Claims 1-4, 8, 10-13, and 16-24 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,511,962. See the above obviousness-type double patenting rejection. In addition, Example 5 of the '962 patent anticipates instant claim 23, and Examples 6 and 7 of the

Art Unit: 1654

'962 patent anticipate instant claims 1-4, 8, 10-13, and 16-24.

15. Claims 9 and 14-17 are rejected under 35 U.S.C. 103(a) as being obvious over U.S. Patent No. 6,511,962. Application of the '962 patent is the same as in the above rejection of claims 1-4, 8, 10-13, and 16-24. The '962 patent does not teach a molar concentration of divalent cation relative to carboxylate groups in the lipopeptide antibiotic. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to determine all operable and optimal divalent cation ratios for the corresponding method step in the '962 patent because reactant ratio is an art-recognized result-effective variable which is routinely determined and optimized in the chemical and extraction arts.

16. Claims 1-4 and 18-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Heinemann et al (U.S. Patent No. 3,126,317). Heinemann et al teach isolating and purifying amphotomycin from filtered broth which also comprises CaCO₃ by acidifying the broth to pH 1.95 with HCl, filtering the acidified broth to give a clear solution, stirring the clear solution with n-butanol, and then separating the two phases. The butanol extracts are then washed with water acidified to pH 2 with HCl, and then stirred with water and the stirred mixture's pH adjusted to pH 6.4. The aqueous extract is then subject to a second acid butanol and alkaline water extraction series to yield a final aqueous extract which is spray-dried. The sodium amphotomycin salt product is then treated with acid to provide the free acid amphotomycin. See, e.g., column 8, lines 61-68; column 9, lines 10-18 and 35-37; and Examples IV-VI. Because divalent calcium ion is present in the fermentation medium and because there are no process steps between fermentation and n-butanol contact which would remove the calcium, inherently the contact between the clear solution containing amphotomycin and the n-butanol will take place in the

Art Unit: 1654

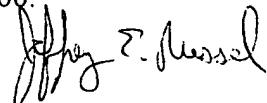
presence of divalent calcium ion in the isolation and purification method of Heinemann et al.

Heinemann et al's step of washing the butanol extracts with acidified water corresponds to Applicants' claimed step of contacting the organic solvent extract of the lipopeptide antibiotic with acid.

17. Claim 10 and 12 are rejected under 35 U.S.C. 103(a) as being obvious over Heinemann et al (U.S. Patent No. 3,126,317). Application of Heinemann et al is the same as in the above rejection of claims 1-4 and 18-24. Heinemann et al do not teach cooling the fermentation broth to a temperature of about 4°C prior to contacting with the n-butanol. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to determine all operable and optimal temperatures for the different processing streams in the isolation and purification method of Heinemann et al because temperature is an art-recognized result-effective variable which is routinely determined and optimized in the chemical and extraction arts.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Bruce Campell can be reached at (571) 272-0974. The fax number for formal communications to be entered into the record is (571) 273-8300; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.



Jeffrey E. Russel
Primary Patent Examiner
Art Unit 1654

JRussel
August 26, 2005